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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,185	09/25/2003	Craig A. Rosen	PS953	5637

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EXAMINER	
DUNSTON, JENNIFER ANN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,185	ROSEN ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 15 and 22, drawn to an isolated nucleic acid molecule, a recombinant vector comprising the nucleic acid molecule, a method of making a recombinant host cell comprising the nucleic acid molecule, and a recombinant host cell comprising the nucleic acid molecule, classified in class 536, subclass 23.5, and class 435, subclasses 320.1, 455, and 325.

This group is composed of multiple distinct inventions, each of which is drawn to a specific nucleic acid molecule (or method of using the nucleic acid molecule) which is chemically, biologically, functionally, and structurally distinct from the others, do not render obvious each other, and thus are patentably distinct from each other.

If Group I is elected, Applicant must elect a single invention that is the nucleic acid molecule and corresponding method drawn to one specific sequence to which the claims will be restricted.

II. Claims 11-13 and 17, drawn to an isolated polypeptide, classified in class 530, subclasses 300 and 350.

This group is composed of multiple distinct inventions, each of which is drawn to a specific polypeptide, and fragments and variants thereof, which is chemically

biologically, functionally, and structurally distinct from the others, do not render obvious each other, and thus are patentably distinct from each other.

If Group II is elected, Applicant must elect a single invention that is the polypeptide, and fragments and variants thereof, drawn to one specific sequence to which the claims will be restricted.

III. Claim 14, drawn to an antibody that binds a polypeptide, classified in class 530, subclass 387.1.

This group is composed of multiple distinct inventions, each of which is drawn to an antibody that binds to a specific polypeptide, which is chemically, biologically, functionally and structurally distinct from the others, do not render obvious each other, and thus are patentably distinct from each other.

If Group III is elected, Applicant must elect a single invention that is the antibody that specifically binds to a specific polypeptide (select the polypeptide to which the antibody binds), drawn to one specific sequence to which the claims will be restricted.

IV. Claim 16, drawn to a method of making an isolated polypeptide, comprising culturing a recombinant host cell under conditions that the polypeptide is expressed, classified in class 435, subclass 69.1.

This group is composed of multiple distinct inventions, each of which is drawn to a specific method of making a polypeptide which is chemically, biologically, functionally, and structurally distinct from the others, do not render obvious each other, and thus are patentably distinct from each other.

If Group IV is elected, Applicant must elect a single invention that is the protein that is produced, drawn to one specific sequence to which the claims will be restricted.

V. Claim 18, drawn to a method for preventing, treating, or ameliorating allergic or asthmatic disorders, comprising administering to a mammalian subject a therapeutically effective amount of a polypeptide, classified in class 514, subclass 2.

This group is composed of multiple distinct inventions, each of which is drawn to a specific method of using a polypeptide which is chemically, biologically, functionally, and structurally distinct from the others, do not render obvious each other, and thus are patentably distinct from each other.

If Group V is elected, Applicant must elect a single invention that is the method of administering a polypeptide (select the polypeptide that is administered), drawn to one specific sequence to which the claims will be limited.

VI. Claim 19, drawn to a method of diagnosing allergic or asthmatic disorders in a subject, comprising determining the presence or absence of a mutation in a polynucleotide, classified in class 435, subclass 6.

This group is composed of multiple distinct inventions, each of which is drawn to a specific method of detecting a mutation in a nucleic acid which is chemically, biologically, functionally, and structurally distinct from the others, do not render obvious each other, and thus are patentably distinct from each other.

If Group VI is elected, Applicant must elect a single invention that is the method of detecting a mutation (select the polynucleotide in which the mutation is identified), drawn to one specific sequence to which the claims will be restricted.

VII. Claims 20 and 24, drawn to a method of diagnosing allergic or asthmatic disorders in a subject, comprising determining the presence or amount of expression of a polypeptide, classified in class 435, subclass 7.1.

This group is composed of multiple distinct inventions, each of which is drawn to a method of detecting a specific polypeptide which is chemically, biologically, functionally, and structurally distinct from the others, do not render obvious each other, and thus are patentably distinct from each other.

If Group VII is elected, Applicant must elect a single invention that is the method of detecting a polypeptide (select the polypeptide that is detected), drawn to one specific sequence to which the claims will be limited.

VIII. Claim 21, drawn to a method for identifying a binding partner to a polypeptide, comprising contacting the polypeptide with a binding partner, classified in class 435, subclass 7.1.

This group is composed of multiple distinct inventions, each of which is drawn to a method of using a specific polypeptide which is chemically, biologically, functionally, and structurally distinct from the others, do not render obvious each other, and thus are patentably distinct from each other.

If Group VIII is elected, Applicant must elect a single invention that is the method of detecting a binding partner to a polypeptide (select the polypeptide that for

which binding partners are detected), drawn to one specific sequence to which the claims will be limited.

IX. Claim 23, drawn to a method of identifying an activity in a biological assay, comprising expressing a nucleic acid in a cell, and detecting an activity in a biological assay, classified in class 435, subclass 4.

This group is composed of multiple distinct inventions, each of which is drawn to a method of using a specific nucleic acid molecule which is chemically, biologically, functionally, and structurally distinct from the others, do not render obvious each other, and thus are patentably distinct from each other.

If Group IX is elected, Applicant must elect a single invention that is the method of detecting a biological activity for a nucleic acid (select the nucleic acid for which an activity is detected), drawn to one specific sequence to which the claims will be limited.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Groups IV and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid molecule can be used in materially different processes as evidenced by the inventions of Groups IV and IX.

Inventions of Group II and Groups V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptide of Group II can be used in a materially different process as evidenced by the inventions of Groups V and VIII.

Inventions Group II and Group IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product can be made by a materially different process, such as isolating the polypeptide from a natural source or chemically synthesizing the polypeptide.

The nucleic acids of Group I, polypeptides of Group II, and the antibodies of Group III are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

The inventions of Groups IV-IX are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups IV-IX comprise steps which are not required for or present in the methods of the other groups: recovering a polypeptide (Group IV), administering to a mammalian subject a therapeutically

effective amount of a polypeptide (Group V), determining the presence or absence of a mutation in a polynucleotide (Group VI), determining the presence or amount of expression of a polypeptide (Group VII), contacting a polypeptide with a binding partner (Group VIII), and detecting an activity in a biological activity (Group IX). The end results of the methods are different: producing a polypeptide (Group IV), preventing, treating or ameliorating allergic or asthmatic disorders in a subject (Group V), diagnosing allergic or asthmatic disorders in a subject based upon a nucleotide sequence (Group VI), diagnosing allergic or asthmatic disorders in a subject based upon the presence or amount of a polypeptide (Group VII), identifying a binding partner for a polypeptide (Group VIII), and identifying a biological activity (Group IX). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Except for the specific relationships described above, the inventions of Groups I-III and Groups IV-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different products of Groups I-III are not necessarily used in or made by the methods of Groups IV-IX.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. For those groups with the same classification, the groups require a different field of search. The search for the invention of Group VII requires search terms related to detecting protein expression (e.g. Western blot, mass spectrometry, etc.),

whereas the search for Group VIII requires the search for specific binding partners and assays such as yeast two-hybrid. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and Examiner time for reviewing the computer search results. Accordingly, the inventions of Groups I-IX are distinct from each other and restriction between the Groups and specific sequences is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with the 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to

maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

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PRIMARY EXAMINER